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09/037,472 03/10/98 DUFF

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HM12/0727

EXAMINER

MYERS, C

ART UNIT

PAPER NUMBER

1655

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DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/037,472

Applicant(s)

DUFF, GORDON W.

Examiner

Carla Myers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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1. This action is in response to Paper No. 14, filed April 11, 2001. Applicants arguments have been fully considered but are not persuasive to overcome all grounds of rejection. All rejections not reiterated herein are hereby withdrawn. This action is made final.
2. Receipt is acknowledged of the Declaration signed by Ian G. Rennie. A new oath or declaration signed by Patrick Richardson and Gordon Duff is required which claims priority to GB 9621129.7.
3. Claims 4-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for predicting a predisposition to clinically significant macular edema by detecting the presence of a genotype selected from the group consisting of (a) IL-1A (-889) 2,2 and IL-1B (-511) 2,2; (b) IL-1A (-889) 1,2 and IL-1B (-511) 2,2; and (c) IL-1A (-889) 2,2 and IL-1B (-511) 1,2, and methods for predicting a patient's predisposition to proliferative diabetic retinopathy wherein the presence of IL-1RN (VNTR) 2,2 is indicative of a decreased likelihood that the patient is predisposed to proliferative diabetic retinopathy, does not reasonably provide enablement for methods which detect the presence of IL-1 RN (VNTR) alleles as indicative of any disease other than proliferative diabetic retinopathy, methods which detect the presence of the IL-1A and ILb alleles as indicative of any disease other than clinically-significant macular edema, methods which detect polymorphisms other than IL-1A (-889), or IL b(-511) or IL-1RN (VNTR) or methods which identify polymorphism patterns in "other genes associated with sight-threatening diabetic retinopathy". The specification does not enable any person skilled

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in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The specification has identified three alleles in the IL-1 gene cluster that are useful for predicting a patient's increased susceptibility to different forms of sight-threatening diabetic retinopathy. In particular, the specification teaches that the presence of IL-1 RN (VNTR) allele 2, 2 provides a protective effect against the development of proliferative diabetic retinopathy (see page 15 of the specification). No protective effect was found in patients which possess only one IL-1RN (VNTR) allele 2. The specification (page 16) also teaches that there is an increase risk of developing clinically-significant macular edema in diabetic patient's possessing one of the following genotypes: (a) IL-1A (-889) 2,2 and ILb (-511) 2,2; (b) IL-1A (-889) 1,2 and ILb (-511) 2,2; or (c) IL-1A (-889) 2,2 and ILb (-511) 1,2. Accordingly, the specification has enabled methods for predicting a patient's predisposition to proliferative diabetic retinopathy wherein the presence of IL-1RN (VNTR) 2,2 is indicative of a decreased likelihood that the patient is predisposed to proliferative diabetic retinopathy and methods for predicting a predisposition to clinically significant macular edema by detecting the presence of a genotype selected from the group consisting of (a) IL-1A (-889) 2,2 and ILb (-511) 2,2; (b) IL-1A (-889) 1,2 and ILb (-511) 2,2; and (c) IL-1A (-889) 2,2 and ILb (-511) 1,2.

The specification is not enabling for methods which detect alleles other than the ILb (-511) allele 2, IL-1A (-889) allele 2 or IL-1RN (VNTR) allele 2 polymorphisms because the specification has not taught any additional alleles that are associated with different forms of sight-threatening

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diabetic retinopathy and it is highly unpredictable as to what other alleles in the IL-1 gene cluster or what other genes in general contain alleles associated with sight-threatening diabetic retinopathy. There is no universal association between the presence of alleles in the IL-1 gene cluster and the occurrence of sight-threatening diabetic retinopathy. The art has not established a correlation between any alleles of IL-1 and the occurrence of disease which would allow for a general relationship to be established between the presence of an IL-1 gene cluster allele and sight-threatening diabetic retinopathy. The specification has not taught any particular attribute of the IL-1 RN (VNTR) allele 2, or ILb (-511) allele 2 or IL-1A (-889) allele 2 that could be extrapolated to other alleles in order to predictably identify other alleles in these genes and other IL-1 genes or any other unstated gene which would be predictive of sight-threatening diabetic retinopathy. Accordingly, there is no predictable means for determining which of the multitude of known and unknown alleles of IL-1 genes and other genes would be associated with sight-threatening diabetic retinopathy. Additional polymorphisms could only be identified by one of skill in the art through extensive trial and error experimentation. In addition, with respect to claim 9, the specification has not identified a single non-interleukin gene which is associated with sight-threatening diabetic retinopathy and has not provided sufficient guidance to enable one of skill in the art to predictably identify "DNA genetic polymorphism patterns for other genes associated with sight-threatening diabetic retinopathy". Case law has established that "(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright* 990 F.2d 1557, 1561. *In re*

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Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that “(t)he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art”. Furthermore, the Court in *Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001 held that “(I)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement”. In the instant case, the specification has identified only the IL-RN (VNTR) 2,2 allele as being correlated with proliferative diabetic retinopathy and haplotypes of IL-1A and ILb carrying at least 3 copies of allele 2 of these genes as being associated with clinically-significant macular edema. Thereby, the scope of the claims does not bear a reasonable correlation to the scope of enablement provided by the specification and undue experimentation would be required to practice the full scope of the claims because this would require randomized searching of IL-1 genes and the entire genome for additional alleles which may be analyzed for their association with sight-threatening diabetic retinopathy. While it may be obvious to try to search for additional polymorphisms correlated with this disease and while it is within the skill of the art to detect sequence variations in general, it is highly unpredictable as to which other, if any, polymorphisms in unspecified known and unknown genes would be correlated with different forms of sight-threatening diabetic retinopathy. The methodology as defined in claim 9 in which polymorphisms are identified in IL-1A, ILb and IL-1RN genes, polymorphisms are identified in “other genes associated with sight-threatening diabetic retinopathy” and then a multiple genetic polymorphism pattern is developed and used to determine risk of sight-threatening diabetic

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retinopathy is considered to be a research project, rather than a methodology that allows one of skill in the art to determine a patient's risk of developing sight-threatening diabetic retinopathy without undue experimentation. The specification does not teach what number of polymorphisms must be carried by a patient in order to determine that the patient has an increased or decreased risk of developing or having sight-threatening diabetic retinopathy. The specification does not exemplify or describe any particular "multiple genetic polymorphism patterns associated with risk of sight threatening diabetic retinopathy" and does not provide sufficient guidance as to how to identify such multiple patterns without extensive experimentation. Furthermore, the specification has established specific correlations between IL-1RN (VNTR) allele 2,2 patterns and proliferative diabetic retinopathy and IL-1A (-889) and ILb(-511) allele 2 patterns and clinically-significant macular edema, but has not established a general correlation between IL-1RN (VNTR) polymorphisms or IL-1A/ILb genotypes and other types of diabetic retinopathy. The specification has not provided any data regarding the occurrence of these IL-1RN and clinically-significant macular edema or the occurrence of IL-1A/ ILb genotypes and proliferative diabetic retinopathy and has not established that polymorphisms associated with clinically-significant macular edema are also associated with proliferative diabetic retinopathy and vice versa. Accordingly, in view of the lack of information provided in the specification as to how to reasonably identify other alleles without undue experimentation and in view of the unpredictability in the art in correlating the presence of an allele with a disease, particularly in correlating the presence of an IL-1

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polymorphism with sight-threatening diabetic retinopathy, the specification has not adequately taught one of skill in the art how to practice the claimed invention as it is broadly claimed.

In the response of Paper No. 14, Applicants state that this rejection has been overcome by the amendment to the claims to recite a method for determining increased risk of sight-threatening diabetic retinopathy and to recite the detection of polymorphisms selected from the group consisting of IL-1RN VNTR allele 2, IL-1 A (-511) allele 2, and ILb (-889) allele 2. Applicants arguments and amendment have been fully considered but are not sufficient to overcome the present grounds of rejection for the following reasons. Firstly, it is noted that claim 9 does not recite any particular alleles for IL-1RN, IL-1A or ILb. Secondly, Claim 9 also requires identifying the genetic polymorphism pattern for "other genes associated with sight-threatening diabetic retinopathy". However, as discussed in the above rejection, the specification has not identified any additional genes associated with sight-threatening diabetic retinopathy and undue experimentation would be required to identify additional genes and polymorphisms within these genes that are correlated with sight-threatening diabetic retinopathy. Thirdly, the rejection is based on the finding that the specification is enabling for methods for predicting a predisposition to clinically significant macular edema by detecting the presence of a genotype selected from the group consisting of (a) IL-1A (-889) 2,2 and ILb (-511) 2,2; (b) IL-1A (-889) 1,2 and ILb (-511) 2,2; and (c) IL-1A (-889) 2,2 and ILb (-511) 1,2, and for methods for predicting a patient's predisposition to proliferative diabetic retinopathy wherein the presence of IL-1RN (VNTR) 2,2 is indicative of a decreased likelihood that the patient is predisposed to proliferative diabetic

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retinopathy. The specification has not established that all forms of sight-threatening diabetic retinopathy are associated with the presence of IL-1A (-889), ILb (-511) or IL-1RN VNTR. Rather, the specification has established only that the combination of alleles of IL-1A (-889) 2,2 and ILb (-511) 2,2; (b) IL-1A (-889) 1,2 and ILb (-511) 2,2; and (c) IL-1A (-889) 2,2 and ILb (-511) 1,2, are correlated with significant macular edema and that the presence of IL-1RN (VNTR) 2,2 is correlated with decreased risk of developing proliferative diabetic retinopathy. For the reasons stated in the above rejection, it is unpredictable as to whether other forms of sight-threatening diabetic retinopathy would be associated with any combination of the IL-1A (-889), IL-1B (-511) or IL-1RN VNTR alleles and undue experimentation would be required to practice the invention as it broadly claimed.

6. Claims 7-10 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7, 8, 10 and 12 are indefinite and confusing over the recitation of "presence at the combined loci of IL-1A plus ILb of at least three copies of the rarer allele for each loci (allele 2) between the two loci". The claims should be amended to clearly set forth a Markush group listing the possible combined IL-1A and ILb patterns, e.g. "wherein said polymorphism pattern is selected from the group consisting of (a) IL-1A (-889) 2,2 and ILb (-511) 2,2; (b) IL-1A (-889) 1, 2 and ILb (-511) 2, 2; and (c) IL-1A (-889) 2,2 and ILb (-511) 1,2.

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In the response of Paper No. 14, Applicants state that the amendments made to claims 7 and 8 obviate the above grounds of rejection. However, the amendment does not clarify what is intended to constitute “the combined loci of IL-1A plus ILb of at least three copies of the rarer allele for each loci (allele 2) between the two loci”

Claim 9 is indefinite and vague over the recitation of “determining the number of polymorphisms” and “identifying diabetic patients expressing a multiple genetic polymorphism pattern” because the claim does not clearly state what constitutes a multiple genetic polymorphism pattern and this phrase is not defined in the specification and there is no statement in the claims as to what number of polymorphisms would be required to determine whether the patient was at risk of having sight-threatening diabetic retinopathy.

In the response of Paper No. 14, Applicants traverse this rejection by stating that the specification “provides specific guidance of multiple polymorphic patterns (e.g. comprising at least three copies of allele 2 at IL-1A (-889) locus and ILb (-511 locus) or zero copies at IL-1 RN (VNTR)”. This argument is not persuasive because the specification does not provide a definition for what constitutes a multiple genetic polymorphism pattern and this term is not clearly defined in the art. While the specification exemplifies a pattern with 3 alleles at IL-1A (-889) and ILb (-511), the claims are not limited to this particular pattern. Rather, the claims include patterns obtained at any IL-1A, ILb and IL-1RN gene and any other genes associated with sight-threatening. The claims do not recite a particular number of polymorphisms or the identity of the

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polymorphisms that constitute the "multiple genetic polymorphism pattern associated with risk of sight-threatening diabetic retinopathy".

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mansfield (Gastroenterology (1994) 106:637-642).

The claims are drawn to kits for identification of a patient's genetic polymorphism pattern. However, it is noted that in claims to products, such as kits, the intended use of the product does not carry weight with respect to the obviousness of the product.

Mansfield teaches methods for detecting polymorphisms at position -511 of the ILb gene and at position -889 of the IL-1A gene and for detecting VNTR alleles of IL-1 RN. In the method disclosed by Mansfield, PCR is performed using primers complementary to sequences flanking the -511 allele of ILb which consist of the same sequences as instant SEQ ID NO: 3 and

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4, primers complementary to sequences flanking the -889 allele of IL-1A which consist of the sequences identical to instant SEQ ID NO: 9 and 10 and primers complementary to sequences flanking the VNTR allele of IL-1 RN which consist of sequences identical to instant SEQ ID NO: 5 and 6 (see Table 2). The method of Mansfield further requires the use of reagents for performing PCR including a means for collecting DNA, DNA amplification means and a DNA detection means. Accordingly, Mansfield teaches a method which requires the use of reagents for the primers of SEQ ID NO: 1, 2, 3, 4, 9 and 10, DNA collection means and DNA amplification means. Mansfield does not teach packaging these reagents into a kit. However, reagent kits for performing DNA detection assays were conventional in the field of molecular biology at the time the invention was made and therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the primers and DNA collection means required to practice the method of Mansfield into a kit for the expected benefits of convenience and cost-effectiveness for practioners of methods for detecting IL-1 RN (VNTR), IL-1A (-889) and ILb (-511) polymorphisms. With respect to claim 1, the amplification reagents, such as polymerase, disclosed by Mansfield are considered to be a means for determining the genetic polymorphism pattern for IL-1A (-889), ILb (-511) and IL-1RN (VNTR) because the amplification reagents allow for the amplification of sequences containing the stated polymorphisms. Thereby, the kits suggested by Mansfield containing DNA sample collection means and amplification reagents meets the limitations of claim 1.

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In the response of Paper No. 14, Applicants traverse this rejection by stating that “in the interest of expediting prosecution and not in acquiescence to the Examiner’s rejection, Applicants have amended claim 2 to delete certain oligonucleotide primers “. However, claim 1 reads on any primer useful for amplifying IL-1A (-889), ILb (-511), and IL-1 RN (VNTR). Furthermore, claim 2 includes primers of SEQ ID NO: 2, 4, 9 and 10, which are identical to the primers disclosed by Mansfield. Applicants further state that the claims are limited to a kit for identifying a diabetic patient’s genetic polymorphism pattern and the cited art does not teach packaging the primers in a kit for the purpose of identifying a diabetic patient’s genetic polymorphism pattern. This argument is not persuasive because in claims to products, such as kits, the intended use of the product does not carry weight with respect to the obviousness of the product. As stated in MPEP 211.02, “When the claim is directed to a product, the preamble is generally nonlimiting if the body of the claim is directed to an old composition and the preamble merely recites a property in the old composition. *Kropa v. Robie*, 187 F.2d at 152, 88 USPQ at 480-481”. The MPEP (2112) further states that “the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable”.

8. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mansfield in view of Kornman (U.S. Patent 5,686,246).

Mansfield teaches methods for detecting polymorphisms at position -511 of ILb and at position -889 of IL-1A and for detecting VNTR alleles of IL-1 RN. In the method disclosed by Mansfield, PCR is performed using primers complementary to sequences flanking the -511 allele

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of ILb which consist of the same sequences as instant SEQ ID NO: 3 and 4, primers complementary to sequences flanking the -889 allele of IL-1A which consist of the same sequences as instant SEQ ID NO: 9 and 10 and primers complementary to sequences flanking the VNTR allele of IL-1 RN which consist of the same sequences as instant SEQ ID NO: 5 and 6 (see Table 2). The method of Mansfield also requires the use of reagents required to perform PCR including a means for collecting DNA, DNA amplification means and a DNA detection means. Mansfield (page 639) further teaches that the IL-1A (-889) polymorphism may be detected by restriction enzyme digestion with *NcoI* and the ILb (-511) polymorphism may be detected by restriction enzyme digestion with *AvaI*. Mansfield does not teach detecting the ILb (-511) polymorphism using the restriction enzyme *Bsu36I* and does not teach packaging the reagents required to detect the polymorphisms into a kit.

However, Kornman (col. 6) teaches that the ILb (-511) polymorphism may be detected using the restriction enzyme *Bsu36I* and specifically teaches that allele 2 of ILb (-511) contains a complete *Bsu36I* site. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Mansfield so as to have also detected allele 2 of the ILb (-511) polymorphism by digestion with *Bsu36I* because Kornman teaches that this is an effective means for directly detecting the presence of ILb (-511) allele 2. The resulting modified method of Mansfield thereby requires the use of reagents for collecting a DNA sample, the primers of SEQ ID NO: 1, 2, 3, 4, 9 and 10, and the restriction enzymes *NcoI*, *AvaI* and *Bsu36I*. In view of the conventionality of reagent kits for performing DNA detection, it

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would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the DNA collection means, restriction enzymes and primers required to practice the method of Mansfield into a kit for the expected benefits of convenience and cost-effectiveness for practioners of methods for detecting IL-1 RN (VNTR), IL-1A (-889) and ILb (-511) polymorphisms.

In the response of Paper No. 14, Applicants traverse this rejection by stating that there is no motivation to combine the teachings of Mansfield and Kornman because Mansfield teaches polymorphisms associated with ulcerative colitis and Kornman teaches polymorphisms associated with periodontal disease. This argument is not convincing because Kornman teaches methods to detect the same polymorphisms taught by Mansfield. Kornman teaches an alternative method for detecting the ILb (-511) polymorphism by digesting with *Bsu36I*. Accordingly, the prior art does provide the motivation to combine the teachings of Mansfield and Kornman because Mansfield discloses methods for detecting the ILb (-511) polymorphism and Kornman provides an alternative and effective means for detecting this polymorphism, i.e. using the restriction enzyme *Bsu36I*. Again, it is pointed out that the motivation to arrive at the claimed kit need not be the same as that supplied by Applicants. The recitation in the claim of a kit with the intended use for the kit of identifying a diabetic patients pattern associated with sight-threatening retinopathy does not distinguish the claimed kits over the kits suggested by the prior art. The skilled artisan would have been motivated to have generated a kit containing the stated restriction enzymes in order to

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have provided a convenient and cost-effective means for performing methods for detecting IL-1 RN (VNTR), IL-1A (-889) and ILb (-511) polymorphisms.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers

July 23, 2001


CARLA J. MYERS
PRIMARY EXAMINER